MEDWATCH VOLUNTARY REPORT

3493021-7-00-01

McNeil Consumer Healthcare
McNeil Consumer Healthcare
Fort Washington, PA 19034-2299

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Approved by FDA on 11/15/93

Mfr report #

UF/Dist report #

FDA use only

A. Patient information

1. Patient identifier: [redacted] confidence
2. Age at time of event: adult or Date of birth:
3. Sex: ( )female (X)male
4. Weight: unk lbs or kgs

B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
- (X) death 4/11/1998 (mo/day/yr)
- ( ) life-threatening
- (X) hospitalization - initial or prolonged
- ( ) disability
- ( ) congenital anomaly
- ( ) required intervention to prevent permanent impairment/damage
- ( ) other:

3. Date of event (mo/day/yr): 4/9/1998

4. Date of this report (mo/day/yr): 04/18/00

5. Describe event or problem

Notification rec'd via Summons & Complaint of DEATH & LIVER FAILURE allegedly associated w/ an unspecified TYLENOL® tablet product. During or before 3/98, pt presented to physician complaining of severe pain in upper abdominal region. Physician reportedly prescribed over-the-counter TYLENOL as needed for pain. At this time, pt began taking 2 tabs of an unspecified TYLENOL product every 8 hours or so. On or about 3/31/98, pt was admitted to hospital for unspecified treatment of upper abdominal pains. After being released 1 wk later without a diagnosis, physician again prescribed TYLENOL as needed for pain. On or about 4/8/98, pt presented to ER complaining of upper abdominal pains. A liver function test was apparently not performed at this time. On or about 4/9/98, pt presented to another ER complaining of the same upper abdominal pain. Pt was admitted to hospital & reportedly diagnosed w/ APAP toxicity. On 4/11/98, pt died. Cause of death was reportedly liver failure due to APAP (TYLENOL) toxicity. (See Sect B6)

6. Relevant tests/laboratory data, including dates

unknown

(Sect B5 cont): APAP levels were not provided. Pt reportedly ingested TYLENOL in accordance with directions furnished by his physicians.

APR 2 6 2000

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

unknown

DSS

APR 2 7 2000

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
- #1 unspecified TYLENOL tablets
- #2

2. Dose, frequency & route used
- #1 2 tabs, q8h or so prn, po
- #2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)
- #1 unknown dates
- #2

4. Diagnosis for use (indication)
- #1 severe pain in upper abdominal region
- #2

5. Event abated after use stopped or dose reduced
- #1 ( ) Yes ( ) No (X) N/A
- #2 ( ) Yes ( ) No ( ) N/A

6. Lot # (if known)
- #1 Unknown
- #2

7. Exp. date (if known)
- #1 Unknown
- #2

8. Event reappeared after reintroduction
- #1 ( ) Yes ( ) No (X) N/A
- #2 ( ) Yes ( ) No ( ) N/A

9. NDC # - for product problems only (if known)

- -

10. Concomitant medical products and therapy dates (exclude treatment of event)

unknown

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)

McNeil Consumer Healthcare
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034

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2. Phone number: 215-273-7303

3. Report source (check all that apply)
- ( ) foreign
- ( ) study
- ( ) literature
- (x) consumer
- ( ) health professional
- ( ) user facility
- ( ) company representative
- ( ) distributor
- ( ) other:

4. Date received by manufacturer (mo/day/yr): 04/17/00

5.
- (A) NDA # 19-872
- IND #
- PLA #
- pre-1938 ( ) Yes
- OTC product (X) Yes

6. If IND, protocol #

7. Type of report (check all that apply)
- ( ) 5-day (X) 15-day
- ( ) 10-day ( ) periodic
- (X) Initial ( ) follow-up #

8. Adverse event term(s)

DEATH LIVER FAILURE

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9. Mfr. report number: 1349943A

E. Initial reporter

1. Name, address & phone #

[redacted]

2. Health professional? ( ) Yes (X) No

3. Occupation: attorney

4. Initial reporter also sent report to FDA: ( ) Yes ( ) No (X) Unk

FDA Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.